EXHIBIT D

GENERAL REPORT OF E. STANTON (STAN) SHOEMAKER, M.D. REGARDING THE TVT and TVT-O MID-URETHRAL SLINGS

The following is my general report regarding the TVT and TVT-O polypropylene slings. My report, including the opinions expressed, is based on my education, training, knowledge, experience, discussions with colleagues, review of medical literature, attendance at medical meetings, review of medical records and deposition testimony specific to this case. It is based on information I currently have reviewed, information cited in this report, and/or have available to me, as set forth in Exhibit A to this report. Inasmuch as I regularly review medical information, attend and/or participate in medical meetings and consultations with my colleagues as part of my continuing medical education and experience, I reserve the right to add to or modify the opinions set forth in this report. All of my opinions expressed in this report are held to a reasonable degree of medical and scientific certainty.

I. Background, Training and Experience

I am a board-certified obstetrician-gynecologist practicing in Corpus Christi Christi, Texas. After receiving my undergraduate degree from the University of Texas, I received my M.D. degree from the University of Texas Medical Branch in Galveston, Texas in 1973. Thereafter, I did my internship and my residency training at Parkland Hospital in Dallas Texas. I am board-certified in obstetrics

and gynecology. Having always been interested in learning and providing to my patients effective, safe and innovative medical treatments and techniques, I was one of the first physicians in Texas to perform laparoscopic surgery for the treatment of gynecologic maladies, including hysterectomies. My practice includes specialized treatment of obstetrics, gynecology, laparoscopic surgery, pelvic floor reconstruction, urinary incontinence and family planning. Because of my experience and surgical skills, I am often referred complicated gynecologic maladies, by my colleagues. Similarly, because of my expertise and specialized knowledge and experience, I am often asked to instruct other obstetrician-gynecologists in the surgical treatment of numerous gynecologic maladies. In fact, I have served as a speaker and preceptor for physicians at Ethicon sponsored training sessions. In those training sessions, I have not only demonstrated the proper way to implant Ethicon's various devices, but I have also discussed with them the information contained in the mesh product IFU's and professional education materials. I can therefore attest to the type information discussed at such sessions and relative knowledge of the physicians attending those sessions as to risks and complications not only associated with pelvic mesh, but also other surgeries that address and treat pelvic floor disorders and SUI. My education and training is set forth in my curriculum vitae attached to this report as Exhibit B.

Having trained from 1973 through 1977 and been in private practice since that time specializing in treatment of pelvic floor disorders and incontinence, I am aware of, and can therefore attest about, the various surgical and non-surgical treatments for such disorders during that period. During my residency, I received extensive training in female pelvic medicine and reconstructive surgery, and thus am familiar and can attest to how physicians are trained and what information is provided during such training. Moreover, because of my continuing medical education, review of medical literature, discussions with colleagues, attendance and participation in medical meetings and teaching other physicians, I am familiar with how this specialized area of medicine is practiced, how physicians obtain information that they rely on in performing surgical procedures, and the manner in which they apprise themselves of and keep up with advances in medicine relevant to the practice of gynecologic medicine. I have seen and experienced and thus can testify to the various revolutionary medical and scientific innovations in this area of medicine which have improved the medical options available to treat women and the quality of life available to them through such innovations.

I have substantial experience with surgical procedures to treat pelvic floor disorders, including pelvic organ prolapse (POP) and stress urinary incontinence (SUI). I have prescribed both non-surgical treatments including physical therapy, use of pessaries and behavior modification. I have performed in excess of 1500

various surgical procedures to treat POP and SUI, including site specific defect repairs, native tissue repair, biologic grafts, in addition to synthetic grafts. I have treated in excess of 700 patients with POP. Specific to the treatment of SUI, I have utilized various non-surgical treatments including prescription antibiotics to treat urinary tract infections (UTI's) and anticholinergic medications, pelvic floor exercises, sacral nerve stimulation (INTERSTIM)], as well as surgical procedures, including anterior colporrhaphy, Marshall-Marchetti-Krantz (MMK) , the Burch procedure, pubo-vaginal sling procedures using autologous, cadaver and graft materials, and mid-urethral sling procedures utilizing synthetic mesh, the latter of which I consider the gold-standard and current standard of care for surgically treating stress urinary incontinence. Consequently, as a result of my experience, as well as my continuing review of the medical literature, professional society publications, discussions with colleagues and attendance at medical meetings, I can provide testimony about the relative risks and benefits of such procedures, the relative efficacy of such procedures, potential complications of such procedures, how patients respond to such treatments, and the relative satisfaction patients have with their respective treatments.

I am also knowledgeable about and can, therefore, attest to, the development of the surgical procedures to treat POP and SUI and how they evolved over time including options available both prior to and after the availability of polypropylene

mesh to treat pelvic floor disorders. The procedures utilizing polypropylene mesh, by and large, were created or developed by physicians seeking better, more effective treatments to improve surgical outcomes in and the quality of life of their patients. Because I have been trained to perform the procedures referenced above, I understand the relative benefits and risks/potential complications associated with each, and how to avoid such complications, if possible, and how best to approach resolution of complications when they do occur.

I have implanted various manufacturers' synthetic mesh products—which all have different surgical approaches. My preferred choice for surgically treating POP utilized the various Ethicon products, including Gynemesh PS™, Prolift, Prolift +M and Prosima. As a result, I performed hundreds of procedures utilizing the Ethicon products for treatment of POP. My preferred choice for treating SUI was and continues to be the slings manufactured by Ethicon inasmuch as I believe them to be the safest and most effective products for surgically treating SUI. I have implanted hundreds of TVT and TVT-Exact products when a retropubic approach is appropriate. Similarly I have performed hundreds of procedures utilizing the TVT-O and TVT-Abbrevo devices when a transobturator approach has been indicated. Importantly, I have implanted Ethicon's mesh products that employed laser-cut mesh as well as mechanically cut mesh. I never saw any clinical difference between the mechanically cut and laser cut mesh. More

specifically, in my experience, there was no difference between the two types of mesh employed in the rates of erosion/exposure/extrusion and dyspareunia in my patients.

It is my opinion that mid-urethral slings are currently considered to be the gold-standard for the treatment of SUI, an opinion which is supported by published literature, as well as the meta-analyses, systematic reviews, published opinion statements and practice guidelines of numerous organizations specializing in treatment of urological and gynecological treatments, including AUGS, AUA, SUFU, IUGA, NICE, AAGL, EAU, and ACOG. I consider these organizations to be highly regarded and respected in my specialized field of practice. I often refer to and rely upon peer-reviewed publications produced by these organizations and their members in forming treatment plans for my patients, as do many of my colleagues, as such publications and papers are often cited as reliable sources for current medical thought and treatment guidelines.

In addition to utilizing the Ethicon products mentioned above, I have also managed complications associated with pelvic mesh procedures, more often than not involving products manufactured by other device manufacturers. I can, therefore, testify regarding the contributing causes and appropriate treatments for such complications.

II. Consulting Fees and Testimonial History

My fee for work in this matter is $400 per hour for review and deposition preparation; $700 per hour for time deposition and for trial preparation; and $5000 per day in trial.

III. Materials Reviewed in Compiling this Report

In addition to the materials previously referenced in this report which serve as the basis for my opinions in this case, I have reviewed, I have reviewed the IFUs and Surgical Technique Guide for Ethicon's various mesh devices, as well as Surgeon's Resource Monographs, Professional Education slides, DVD's, animations and surgical videos, Patient Brochures, and other professional education materials relating to Ethicon's mesh devices, including the devices specifically at issue in this case.

This report contains my opinions in this case as of the date of this report. My conclusions and opinions are based on the facts presented in the depositions, any physical examinations performed, complaints of the patient, operative reports and medical records reviewed, as well as the educational materials routinely provided by Ethicon both for the patient and practitioner, and information which is

available in the usual and customary practice of female pelvic medicine and reconstructive surgery using an evidence-based approach.

I reserve the right to amend this report as other information relevant to this matter becomes available to me, including reports/results of any medical examinations performed after the date of this report, and as additional medical records become available.

IV. URINARY INCONTINENCE

A. Background

Urinary incontinence, the involuntary leakage of urine, is a common condition in women, particularly as they age. Incontinence can result from many different abnormalities, including not only particular illnesses that result in urine leakage, but also from pelvic floor dysfunction and abnormalities in the lower urinary tract. Leakage may occur in different settings thereby defining the type of incontinence at issue. For example, stress urinary incontinence (SUI), occurs with physical exertion such as lifting, bending, coughing, sneezing, or other activity or movement. Urgency incontinence occurs in the setting of bladder muscle contraction causing a sudden need to urinate resulting in involuntary urine leakage. Mixed urinary incontinence includes both SUI and urgency incontinence.

These conditions can have a debilitating effect on women, both physically and emotionally, and can significantly affect a woman's quality of life. Urinary incontinence can lead to maladies such as urinary tract infections, pressure ulcers, and cellulitis, and can also have a tremendous social impact resulting in a woman limiting her social activities and relationships caused by fear of embarrassment. Additionally, urinary incontinence can impact a woman economically by impeding her ability to perform occupational tasks because of a need to constantly be near a bathroom. Similarly, incontinence can have a significant effect on sexual function resulting in a woman refraining from sex because of incontinence during sex or a fear that incontinence will occur.

The cause of urgency incontinence is not well-understood, and can occur in both women and men. In some patients, urgency incontinence can often be successfully treated or controlled with medication; other treatments include behavior modification, prescription of anticholinergic drugs, sacral nerve stimulation and Botox injection in some cases.

SUI is primarily caused by compromise of urethral support due to the relaxation of muscle, fascia, and other tissue comprising the pelvic floor. Risk factors for SUI include previous pelvic surgery including hysterectomy, pregnancy with vaginal delivery, increasing age, obesity, metabolic disease such as diabetes,

smoking and family history, to name a few. Any condition that can cause weakening of the pelvic floor structures can cause or contribute to SUI.

The medical community's understanding of SUI has evolved over time leading to development of varying treatments and approaches to effective treatment. While early surgical treatment of SUI focused on reconstruction of support at the bladder neck, over time the focus shifted to the support structure of the mid-urethra. Unlike treatment of urgency incontinence, there are no medications approved in the United States for treatment of SUI. While there are non-surgical treatments for SUI, surgical treatments are by far more effective in obtaining long-term success and in many instances cure.

Nonsurgical options for treating SUI include pelvic floor muscle training, injection of bulking agents, use of incontinence pessaries and Kegel exercises. These options have limited long-term efficacy and are often not preferred by women seeking a longer-term solution. They are also inconvenient to many women. For example, a pessary, which is a device inserted into the vagina to support the pelvic area and urethra, must be removed for cleaning or sexual activity and can lead to vaginal discharge, odor, pain, bleeding and erosion. Many women who elect to try these more conservative non-surgical options initially often ultimately elect a surgical route.

Historically, more than 100 surgical procedures have been employed to treat SUI. These procedures evolved over time as physicians constantly sought to find more effective procedures to treat this very troublesome condition. The most common surgical options employed in the last decade have included: Kelly Plication stitching, the Burch colposuspension, native/biologic tissue slings and most often, synthetic slings. Other types of surgeries to treat SUI which were used in the past, included the Marshall-Marchetti-Krantz (MMK) procedure, anterior colporrhaphy and needle suspension procedures. Their use declined as more innovative and effective treatment evolved and began to be recommended by medical associations which largely dictate current standards of care.

No surgical options for treating SUI are risk-free. Rather all such procedures carry the following risks:

Damage to organs like the bladder
Ureteral injury
Damage to bowel
Damage to vessels
Damage to nerves
Anesthesia risks
Wound complications some requiring surgical intervention
Infection
Incisional hernia
Wound dehiscence (wound edge separation)
Seroma or hematoma
Granulation tissue or stitch granulations
Inflammation
Bleeding
Need for blood transfusion
Blood clot
DVT
Fistula
Erosion of suture (ie, into bladder)
Urinary tract infection (recurrent)
Need for repeat surgery
Development of vaginal wall prolapse after Burch surgery

Recurrent cystitis (urinary bladder inflammation)
Catheter complications
Voiding dysfunction / difficulty
De novo detrusor overactivity
De novo urgency urinary incontinence
Urinary retention
Urinary frequency
Need for self-catheterization
Persistent Voiding dysfunction
Voiding dysfunction leading to surgical revision
Pain
Pain to the groin
Pelvic pain
Dyspareunia (Pain with sex)
Numbness or weakness from the surgery
Gastrointestinal problems
Bowel adhesion
Ileus / bowel obstruction
Abdominal scar

The only risk unique to the use of pelvic mesh in such surgery is the risk of mesh erosion, exposure or extrusion. (FDA March 27, 2013 Statement, Considerations about Surgical Mesh for SUI; AUA October 2013 Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence). However, colposuspension and fascial sling procedures often rely on the use of permanent sutures, which can also lead to erosion, and wound complications also occur with these procedures.

All pelvic surgeons are trained in the procedures to treat SUI in their residencies. Information about these risks provided to physicians in such training. Moreover, as part of a physician's continuing medical education—which is required to maintain active licenses and credentials—these risks are continually addressed in the published literature. Accordingly, it is my opinion that these risks do not need to be included professional materials and instructions for use (IFU's) for products employed in such procedures such as the TVT products.

B. Ethicon's TVT Line of Products

1. Development of the TVT Line of Products

Ethicon's TVT line of products are comprised of monofilament, large pore (macroporous) Prolene polypropylene, the most common type of synthetic material used in sling procedures, and, importantly, the material having the

longest track record of safe and effective use. Permanent Prolene polypropylene sutures have been used safely in patients for many decades in all types of surgery with little or no reported problems with the suture material, such as degrading, particle loss, enhanced scarring, cytotoxicity or increased infection rates. Synthetic polypropylene mesh has been safely and effectively used for decades in various abdominal procedures. Abdominal surgeons began utilizing such mesh primarily to reduce the recurrence rate of hernias repaired by traditional non-mesh surgery. As word spread about the effectiveness of polypropylene mesh to treat hernias and reduce hernia recurrence, pelvic surgeons began incorporating such mesh in their surgical prolapse repairs, as well as their surgical treatment of SUI with mid-urethral slings in an effort to improve outcomes for their patients suffering from pelvic floor disorders. Some pelvic surgeons were using polypropylene mesh in pelvic surgery as early as the 1960's in performing abdominal sacral colpopexy and the 1970's for surgical treatment of SUI.

Many of the surgical procedures and devices currently employed were developed by physicians continually seeking safe and effective treatments to improve outcomes in their patients. The TVT and TVT-O slings were developed in much the same way. In the early 1990's Dr. Ulmsten and his colleagues sought to improve the outcomes in their surgical treatment of SUI's.

Prior to that time much of the surgical treatment of SUI had focused on providing enhanced support to the bladder neck. Such surgery, however, was invasive and not as effective as Dr. Ulmsten and his colleagues preferred. They began using a sling made of synthetic polypropylene with much success. This new procedure was revolutionary in that it employed a sling-type device implanted at the mid-urethra instead of the bladder neck. Their efforts resulted in development of the TVT retropubic sling (TVT). (Petros P. Creating a gold standard surgical device: scientific discoveries leading to TVT and beyond: Ulf Ulmsten Memorial Lecture 2014. Int Urogynecol J. 2015; 26:471-6.) See also ((Petros PE, Ulmsten UI. An integral theory and its method for the diagnosis and management of female urinary incontinence. Scand J Urol Nephrol Suppl. 1993; 153:1-93; Ulmsten U, et al. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 1996; 7:81-5; Falconer C, et al. Influence of different sling materials on connective tissue metabolism in stress urinary incontinent women. Int Urogynecol J Pelvic Floor Dysfunct. 2001; 12 Suppl 2:S19-23.) (Falconer C, et al. Clinical outcome and changes in connective tissue metabolism after intravaginal slingplasty in stress incontinent women. Int Urogynecol J Pelvic Floor Dysfunct. 1996; 7:133-7.)

2. TVT and TVT-O

The TVT is a **mid-urethral** sling which is implanted intravaginally using a retropubic approach. The TVT mesh is attached to a needle which is inserted into the vagina through an incision creating a mid-urethral sling effect. The needles are passed through the vagina, essentially scraping the back of the pubic bone and exiting the lower abdomen. It is placed without tension to support the mid-portion of the urethra. Cystoscopy is required during the procedure to insure there is no bladder injury. Intravaginal SUI surgery utilizing a mesh sling is minimally invasive, thereby minimizing some complications associated with abdominal surgery, is a quicker procedure using either local or minimal anesthesia, and carries less recovery time and time away from work or one's daily activities. Moreover, it provides almost immediate efficacy. Therefore, its use is preferred by many surgeons and patients. In fact, many, if not most gynecologic, urologic, and urogynecologic professional societies recognize the synthetic mesh slings, such as the TVT products to be the gold standard for surgically treating SUI. See guidelines of the AUA, AUGS, IUGS, to name a few.

However, while no surgery is risk-free, and all pelvic surgery carries a risk of damage to surrounding organs and tissue, including bladder injury, some surgeons utilizing the TVT were experiencing increased bladder injury using a

retropubic technique. For that reason, a mid-urethral sling employing a transobturator approach was developed, the TVT-O. Like the TVT, the TVT-O mid-urethral sling is comprised of large-pore, monofilament, polypropolene mesh, which is implanted intravaginally. However, rather than passing retropubically, the arms of the TVT-O are passed through the obturator foramen, minimizing the risk of bladder perforation. By developing the TVT-O, physicians then had a choice, based on their own preference and the particular characteristics of their individual patients, of devices to employ in treating SUI. Neither design was necessarily better or safer, they each had different characteristics while offering a safe and effective treatment for SUI.

3. Data Proving the safety and efficacy of TVT and TVT-O

The TVT and TVT-O have been studied extensively, in over 100 randomized controlled trials (RCTs) and many more other studies. In fact, no other synthetic mesh product utilized in the treatment of pelvic floor dysfunction has been studied more than the TVT and TVT-O. These studies demonstrate that the TVT and TVT-O are among the safest and most effective treatments for SUI. Some of the publications attesting to this fact include: (Albo ME., N Engl J Med. 2007;356:2143-55); (Richter H, et al.

Patient Related Factors Associated with Long-Term Urinary Continence After Burch Colposuspension and Pubovaginal Fascial Sling Surgeries. J Urol. 2012; 188:485-9.);(Ford AA, Rogerson L, Cody JD, Ogah J. Mid-urethral sling operations for stress urinary incontinence in women. Cochrane Database Syst Rev. 2015 Jul 1;7:CD006375. PMID: 26130017); (Schimpf MO, et al. Society of Gynecologic Surgeons Systematic Review Group. Sling surgery for stress urinary incontinence in women: A systematic review and meta-analysis. Am J Obstet Gynecol. 2014; 211:71.e1-71; AUA 2012 update to SUI Guidelines. https://www.auanet.org/common/pdf/education/clinical-guidance/Incontinence.pdf); (Nilsson CG, et al. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J. 2013; 24:1265-69); Schimpf MO, et al. Society of Gynecologic Surgeons Systematic Review Group. Sling surgery for stress urinary incontinence in women: A systematic review and meta-analysis. Am J Obstet Gynecol. 2014; 211:71.e1-71.); Ogah J, Cody JD, & Rogerson L. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. Cochrane Database Syst. Rev. CD006375 (2009); Rehman H, Bezerra CC, Bruschini H, Cody JD. Traditional suburethral sling operations for urinary incontinence in women.

Cochrane Database Syst. Rev. CD001754 (2011); Novara, G., et al., Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. Eur Urol, 2010. 58(2): p. 218-38.); Ogah J, et al. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. Cochrane Database Syst Rev. 2009 Oct 7;(4):CD006375; Ogah J, et al. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women: a short version Cochrane review. Neurourol Urodyn. 2011; 30:284-91); Tommaselli GA, et al. Medium-term and long-term outcomes following placement of mid-urethral slings for stress urinary incontinence: a systematic review and meta-analysis. Int Urogynecol J. 2015; 26:1253-68.); Ford AA, Rogerson L, Cody JD, Ogah J. Mid-urethral sling operations for stress urinary incontinence in women. Cochrane Database Syst Rev. 2015 Jul 1;7-CD006375. PMID: 26130017); (Novara G, et al. Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. Eur Urol. 2010; 58:218–38); (Nguyen JN, et al. Perioperative complications and reoperations after incontinence and prolapse surgeries using prosthetic implants. Obstet Gynecol. 2012;

119:539-46); (Unger CA, et al. Indications and risk factors for midurethral sling revision. Int Urogynecol J. 2015.

These published data include comparisons of the TVT products to types of procedures utilized in treating SUI, including the Burch colposuspension, use of autologous fascia and other biologic material. They also discuss and cite data relating to the efficacy of the various products studied and procedures to which they are compared. (*See* the many and varied medical articles listed in Exhibit A to this report.) Additionally, they evaluate and report the relative rates of revisions for urinary retention and/or other problems, as well as the relative safety of the TVT products compared not only to other mesh products, but also to other SUI surgical procedures. Risk factors studied include the risks of dyspareunia, pain, wound complications (See data from the SISTEr and TOMUS trials), to name a few.

The most common complications from implantation of synthetic mesh involves the risks of mesh exposure, erosion, or extrusion, complications which have been well-known among pelvic surgeons for many years. Mesh exposure/erosion/extrusion are often the result of surgeon technique or characteristics of the patients themselves, such as patients who have metabolic disorders that affect wound healing, patients who are smokers, and

menopausal patients whose estrogen depletions results in thinning vaginal tissue leading to erosion/exposure/extrusion. Additionally, the risk of material erosion/exposure/extrusion exists with the use of other materials employed in non-mesh pelvic surgery, like the use of the many different sutures utilized in such procedures. In any event, the overall data show that the rates of mesh exposure with TVT and TVT-O are in the 1 - 2.5% range, and are manageable through either conservative treatment with estrogen cream or minimally invasive procedures to trim such mesh which can be performed in either the office in some instances or as outpatient surgery. In fact, some exposures can resolve on their own. (See Ford 2015 Cochrane Review). While there are rare reports, in my experience and based on my review of the literature, of groin/leg pain associated with the obturator-type slings, including the TVT-O, such reports are typically transient and not long term.

The clinical data demonstrate that the TVT and TVT-O macroporous Prolene polypropylene mesh is biocompatible, has a minimal inflammatory response, and allows for adequate tissue ingrowth, the mechanism by which mesh ultimately provides the necessary structural support lacking in women experiencing SUI. (Falconer C, et al. Influence of different sling materials on connective tissue metabolism in stress urinary incontinent women. Int

Urogynecol J Pelvic Floor Dysfunct. 2001; 12 Suppl 2:S19-23.) This data likewise shows that the TVT and TVT-O mesh is not associated with a significantly increased risk of infection over that generally associated with SUI and vaginal surgery. The data in women does not support any claim that the TVT and TVT-O mesh is cytotoxic or causes an adverse inflammatory response, sarcoma or cancer. Given the numbers of women in whom such mesh has been implanted, if there were any merit to a claim of the possible cytoxicity of the TVT mesh, I would certainly expect valid data to demonstrate that claim in replicable studies. There are no such data. Similarly, there is no reliable data to support any claim that the manner in which the mesh is trimmed or cut—whether mechanically- or laser-cut—has any clinical relevance or significance. Likewise, there is no reliable data demonstrating that the TVT or TVT-O mesh degrades or loses particles in situ, or that if it did it such degradation/particle loss has any clinically significant effect. Finally, I am aware of no reliable data demonstrating that when implanted correctly, the TVT or TVT-O unnecessarily rope, curl or becomes unexpectedly stiff with any clinical effect. Similarly, I have observed no such clinically relevant effects in my experience treating hundreds of patients with the TVT and TVT-O.

In light of the voluminous data on the safety and efficacy of the TVT mesh, there is no validity to or reliable scientific data supporting any claim that other materials, such as Vypro or Ultrapro are safer, more effective alternative materials and should be used. The data are clear that the TVT mesh is light-weight and sufficiently macroporous to safely and effectively treat SUI.

Overall, the voluminous data from studies evaluating the TVT and TVT-O are largely high-level studies with long-term follow-up, and overwhelmingly demonstrate that the TVT and TVT-O are very safe and effective, especially when compared to alternative treatments. See Svenningsen R, et al. Long-term follow-up of the retropubic tension-free vaginal tape procedure. Int Urogynecol J. 2013; 24:1271-78;Serati M, et al. Tension-free vaginal tape for the treatment of urodynamic stress incontinence: efficacy and adverse effects at 10-year follow-up. Eur Urol. 2012; 61:939-46; Serati M, et al. TVT for the treatment of urodynamic stress incontinence: Efficacy and adverse effects at 13-year follow-up. Neurourol Urodyn. 2015 Oct 19; Heinonen P, et al. Tension-free vaginal tape procedure without preoperative urodynamic examination: long-term outcome. Int J Urol. 2012; 19:1003-9; Olsson I, et al. Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence: a

retrospective follow-up 11.5 years post-operatively. Int Urogynecol J. 2010; 21:679-83.

There are no reliable scientific data that demonstrate or even suggest that polypropolene mesh devices, including the TVT and TVT-O are associated with a risk of cancer and reliance by Plaintiff's experts on MSDS sheets and data in rats while attempting to extrapolate to humans is unreliable and improper methodology. (Moalli P, et al. Polypropylene mesh: evidence for lack of carcinogenicity. Int Urogynecol J. 2014; 25:573-6; King AB, Goldman HB. Current controversies regarding oncologic risk associated with polypropylene mid-urethral slings. Curr Urol Rep. 2014; 15:453.) There are no epidemiologic data which shows that there is a statistically significant risk compared to the background rate of malignancy. King reported a series of 2,361 polypropylene mid-urethral slings with a follow-up extending up to 122.3 months and the rate of cancer formation was 0.0 % and no sarcomas were reported. (King AB, et al. Is there an association between polypropylene mid-urethral slings and malignancy? Urology 2014; 84:789-92). As observed by AUGS and SUFU in their 2014 Frequently Asked Questions by Providers on MUS for SUI:

> Tumors related to the implantation of surgical grade polypropylene for mid-urethral slings in humans have never been reported. There is no

> compelling evidence supporting human malignant transformation related to polypropylene despite the millions of individuals implanted with various forms of this material spanning well over a half century world-wide. The possibility that biomaterial prosthetic devices could cause tumors or promote tumor growth has been the focus of extensive research by both clinicians and biomaterial researchers.

(McGregor, D.B., et al., Evaluation of the carcinogenic risks to humans associated with surgical implants and other foreign bodies - a report of an IARC Monographs Programme Meeting. International Agency for Research on Cancer. Eur J Cancer, 2000. 36(3): p. 307-13; Ratner, B.D., et al., eds. Biomaterials Science: An Introduction to Materials in Medicine - 3rd Edition. 2013, Academic Press: Waltham, MA.)

4. Claims that TVT products should be comprised of a different mesh and should have a different design.

Claims that alternative designs and different types of mesh used in the TVT line of products would result in a safer and more effective, in my opinion, are meritless and unsupported the data discussed above, the published, peer-reviewed literature and materials from the professional societies mentioned above, and my own experience.

In 1997, the Amid mesh classification was published classifying various hernia mesh primarily based on pore size and the relative pore size in relation to rates of infection and tissue integration. Given the classification's acceptance among physicians and scientists, it was applied to classification of pelvic mesh as well. This classification essentially categorized mesh as either macroporous (pore size of >75 μm), or microporous(< 75 μm). Macroporous is the preferred mesh in pelvic surgery because it allows passage of leukocytes and macrophages 9–20 μm in size into the pores of the mesh, an important factor in minimizing bacterial infiltration and, therefore, infection. Infection-causing bacteria are often very small (<1 micron in size) and can infiltrate small-pore mesh, but the macrophages and leukocytes necessary to fight off such bacteria cannot. Mesh pore size >75 μm, like that used all the TVT products, allows macrophages and leukocytes to infiltrate the mesh and minimize the risk of infection. Additionally, the larger pore allows for the patient's tissue to integrate into the interstices of the mesh thereby providing for better support, prohibiting encapsulation. Type 1 mesh is a macroporous (pore size > 75 μm), monofilamentous polypropylene mesh which has been the standard mesh used in pelvic floor prolapse surgery. Gynemesh PS™ (Prolene Soft), the mesh used in the Prolift products and Prosima is a type 1 mesh with a pore size of approximately 2.5 mm or 2,500 μm, and is the choice of mesh

preferred by many pelvic floor surgeons for the treatment of both prolapse and stress urinary incontinence. The pore size of Prolift + M, which is composed of Gynemesh PS™ and monocryl (Ultrapro) is 3.5 mm post-absorption, thereby meeting the Amid classification as a monofilament lightweight Type 1 mesh.

Notably, the pore-size of the TVT products are significantly larger than 75 microns. I am aware of no reliable data, nor is it my experience, that the pores in the above meshes collapse once implanted. It is my opinion that the tissue integration with these products is sufficient to prevent pore collapse.

Types 2, 3, and 4 meshes such as Gore-Tex™ and Mersilene™, were formerly used in pelvic surgery; they are microporous (pore size < 75 μm), multifilament meshes which have largely been abandoned for use in transvaginal surgery as they were found to be prone to infection, associated with greater wound complications, and did not incorporate well into native tissue.

Type 1 mesh works with the body's host defense mechanisms promoting what is referred to as local inflammatory reaction and formation of fibrous tissue (like scarring); that inflammation often decreases with time. Chronic inflammatory cells commonly present in vaginal tissue are often

observed near implanted mesh. This host defense mechanism is a normal foreign body response and is expected, a fact well-known to surgeons implanting foreign material, including pelvic mesh. Accordingly, the presence of chronic inflammatory cells reported in a pathology report evaluating explanted pelvic mesh of does not indicate an unexpected or abnormal finding, nor does it represent an adverse biologic reaction or defective mesh.

The types of mesh used in pelvic surgery evolved over time. The polypropylene mesh used for prolapse repair was initially Gynemesh which was significantly lighter than traditional abdominal hernia meshes. Gynemesh PS™, a second generation mesh, was lighter than Gynemesh and improved elasticity as described by the original TVM group. (Berrocal J, et al. The TVM Group. Conceptual advances in the surgical management of genital prolapse, J Gynecol Obstet Biol Reprod 2004; 33:577-587.) Additional meshes were developed in this ever-evolving effort to provide safe and effective treatment options for pelvic floor disorders, including Ethicon- manufactured Vypro and Ultrapro, meshes commonly utilized in hernia surgery.

Vypro mesh (types I and II), comprised of polypropylene and polyglactin (PGA) has greater elasticity and larger pores, and was developed as a treatment for incisional hernias. While initial experimental and clinical

studies of Vypro mesh were promising in the hernia context, studies of Vypro in the context of pelvic floor repair did not provide the same results. Lim and his colleagues reported that incorporating Vypro II as an overlay into a posterior colporrhaphy was associated with an unacceptably high incidence of complications. [Lim, Int Urogynecol 2007]. Jacquetin and his colleagues reported poor tolerance for the Vypro used to treat POP, as well as high rates of erosion and problems with cicatrisation, retraction and rigidity. Denis S, Pelvic Organ Prolapse Treatment by the vaginal route using a Vypro® composite mesh: Preliminary results about 106 cases. 2004 ICS IUGA. While limited in clinical use, Ultrapro showed some potential for reducing the inflammatory reaction in animal studies and was later used in Prolift +M, although later comparative studies showed that complications did not differ significantly from Prolift.

The voluminous studies of the TVT products as well as the mesh utilized in the TVT products demonstrate the safety and efficacy of those products, which is why they are considered the gold standard for treatment of SUI.

V. TVT and TVT-O Information Provided to Physicians

While Ethicon made available to surgeons IFUs, patient brochures, a Surgeon's Resource Monograph, a technical guide and made training sessions for the use of its devices, including the TVT line of products, available to surgeons, it is my opinion, as a pelvic floor reconstructive surgeon, that while those materials are important, neither I nor my colleagues, nor any surgeon that I know of or have trained, rely on IFU's or instructions from device manufacturers as our primary means of learning about the products used in surgery, the methods of using or implanting surgical prosthetics, or risks associated with their use. Rather, we learn how to perform any surgery, including SUI surgery utilizing pelvic mesh, in residency, fellowship and by proctorship. It is my experience that many surgeons never read the IFU, or other materials provided by manufacturers. As practicing physicians, we have little or no time to meet with manufacturers' representatives, and given the number of prescription products and devices we either prescribe or utilize on a regular basis, we neither expect nor rely on pharmaceutical companies to provide us with our primary means of understanding the risks associated with products they sell. Rather, we rely on published medical articles, presentations at professional meetings, and discussions with colleagues. We rely on

evidence-based medicine and our own experience to dictate our treatment choices.

The original TVT IFUs warned of several risks including, but not only, damage to vessels, nerves, bladder and bowel, inflammation, extrusion and erosion. Any surgeon practicing pelvic reconstructive surgery understands that these complications may cause pain and dyspareunia, as well as the need for additional surgery.

I have reviewed the professional education materials offered to surgeons by Ethicon relating to their pelvic mesh products, and it is my opinion that Ethicon adequately apprised physicians practicing pelvic reconstructive surgery of the risks associated with the use of the TVT line of products, and that risks associated with the these products were adequately described in their respective IFUs and other professional education materials.

The Patient Brochures available for dissemination by physicians as a supplement to a physician's specific discussion of the product with their patients were never intended to supplant the discussion by the doctor. Nevertheless, they provided adequate information to lay persons to supplement discussions with their physicians regarding treatment options SUI surgery.

Ethicon's professional education materials and training were most helpful in informing physicians of the proper use and risks associated with its products. While in my opinion it is not a device manufacturer's responsibility to train surgeons, such training is a valuable service to physicians and offers them not only the opportunity to continue their medical education and knowledge, but provides access to other, and in some instances, more experienced surgeons, and provides them with the opportunity to improve their surgical skills. The instructions and professional materials provided by Ethicon, make clear that their mesh products should be used by experienced physicians. The training and other educational opportunities provided by Ethicon allow surgeons to gain knowledge and experience regarding Ethicon's products. Professional education offered by Ethicon has been more than adequate, and in fact exceptional, in my opinion. In my opinion, Ethicon was very responsible and thorough in the way they studied their products and trained physicians in how to use them.

The opinions reflected in this report are based on information currently available to me. I reserve the right to modify or amend these opinions as new information becomes available.

E. Stanton Shoemaker, M.D.